

CRITERIA FOR PRIOR AUTHORIZATION

Minimum Requirements Prior Authorization

BILLING CODE TYPE For drug coverage and provider type information, see the [KMAP Reference Codes webpage](#).

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Non-covered **FDA-approved** indications, if any, are also listed in Table 1. Per Section 1927 of the Social Security Act [42 USC § 1396r-8(d)(2)], as amended by P.L. 111-148 § 2502, certain drugs, or their medical use, may be excluded from coverage or otherwise restricted.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed age and dosing limits listed in Table 1.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved indication, age, and dosing limits.¹⁻¹⁸

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
Amikacin (Arikayce®)	As part of combination therapy for refractory Mycobacterium avium complex (MAC) lung disease in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen.	≥ 18 years	590mg nebulized inhalation once per day.	N/A
Cannabidiol (Epidiolex®)	Treatment of seizures associated with Lennox-Gastaut syndrome (LGS).	≥ 2 years	10mg/kg orally twice daily.	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
	<u>Treatment of seizures associated with Dravet syndrome (DS).</u>			
<u>Clobazam (Onfi[®], Sympazan[™])</u>	<u>Adjunctive treatment of seizures associated with LGS.</u>	<u>≥ 2 years</u>	<u>≤30kg: 20mg orally daily.</u> <u>>30kg: 40mg orally daily.</u>	<u>N/A</u>
<u>Denosumab (Xgeva[®])</u>	<u>Prevention of skeletal-related events in multiple myeloma and in patients with bone metastases from solid tumors.</u> <u>Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.</u> <u>Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.</u>	<u>≥18 years;</u> <u>≥13 years and skeletally mature for those with giant cell tumor of bone.</u>	<u>120mg SQ every 4 weeks.</u> <u>For giant cell tumor of bone or hypercalcemia of malignancy: Additional 120mg SQ on days 8 & 15 are allowed in the first month.</u>	<u>N/A</u>
<u>Dextromethorphan/quinidine (Nuedexta[®])</u>	<u>Treatment of pseudobulbar affect (PBA).</u>	<u>≥ 18 years</u>	<u>20mg/10mg orally every 12 hours.</u>	<u>N/A</u>
CFTR Modulators				
<u>Eluxacaftor/tezacaftor/ivacaftor (Trikafta[™])</u>	<u>Cystic fibrosis with ≥1 F508del mutation.</u>	<u>≥ 12 years</u>	<u>200mg/100mg/300mg total per day, 2 combination tablets (100mg/50mg/75mg/tablet) orally in the morning and 1 ivacaftor 150mg tablet in the evening.</u>	<u>N/A</u>
<u>Eluxadoline (Viberzi[™])</u>	<u>Irritable bowel syndrome with diarrhea (IBS-D).</u>	<u>≥ 18 years</u>	<u>100mg orally twice daily.</u>	<u>N/A</u>
<u>Ivacaftor (Kalydeco[™])</u>	<u>Cystic fibrosis with ≥1 CFTR gene mutation that is responsive to ivacaftor based on clinical and/or in vitro assay.</u>	<u>≥ 6 months</u>	<u>300mg-150mg total per day orally every 12 hours.</u>	<u>N/A</u>
<u>Lumacaftor/ivacaftor (Orkambi[®])</u>	<u>Cystic fibrosis with homozygous F508del mutation.</u>	<u>≥ 2 years</u>	<u>800mg/500mg total per day, 2-5 years, <14kg: 100mg/125mg packet orally every 12 hours.</u>	<u>N/A</u>

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
			<u>2-5 years, ≥ 14kg: 150mg/188mg packet orally every 12 hours.</u> <u>6-11 years: 2 tablets (100mg/125mg/tablet) orally every 12 hours.</u> <u>≥ 12 years: 2 tablets (200mg/125mg) orally every 12 hours.</u>	
<u>Mecasermin (Increlex®)</u>	<u>Growth failure in severe primary insulin-like growth factor-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.</u>	<u>≥ 2 years</u>	<u>0.12mg/kg SQ twice daily.</u>	<u>N/A</u>
<u>Nintedanib (Ofev®)</u>	<u>Treatment of idiopathic pulmonary fibrosis.</u> <u>Treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype.</u> <u>Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease.</u>	<u>≥ 18 years</u>	<u>1 capsule (150mg) orally twice daily.</u>	<u>N/A</u>
<u>Ospemifene (Osphena®)</u>	<u>Treatment of moderate to severe dyspareunia or moderate to severe vaginal dryness due to menopause.</u>	<u>≥ 18 years and unable to become pregnant</u>	<u>60mg orally once daily.</u>	<u>N/A</u>
<u>Pirfenidone (Esbriet®)</u> <u>Pirfenidone (Esbriet®)</u>	<u>Treatment of idiopathic pulmonary fibrosis</u> <u>Treatment of idiopathic pulmonary fibrosis</u>	<u>≥ 18 years</u> <u>≥ 18 years</u>	<u>1 tablet (801mg) orally three times daily.</u> <u>1 tablet (801mg) orally three times daily.</u>	<u>N/A/N/A</u>
<u>Rufinamide (Banzel®)</u>	<u>Adjunctive treatment of seizures associated with LGS.</u>	<u>≥ 1 year</u>	<u>45mg/kg/day up to 3,200mg orally per day.</u>	<u>N/A</u>
<u>Solifenacin (Vesicare LS™)</u>	<u>Pediatric neurogenic detrusor overactivity</u>	<u>2-17 years</u>	<u>9-15 kg: 4 mg orally per day</u>	<u>N/A</u>

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
			>15 to 30 kg: 5 mg orally per day >30 to 45 kg: 6 mg orally per day >45 to 60 kg: 7 mg orally per day >60 kg: 10 mg orally per day	
Stiripentol (Diacomit®)	Treatment of seizures associated with Dravet syndrome taking clobazam.	≥ 2 years	3,000mg/day orally per day.	N/A
Telotristat ethyl (Xermelo™)	Carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in those inadequately controlled by SSA therapy.	≥ 18 years	250mg orally three times daily.	N/A
Tezacaftor/ivacaftor (Symdeko®)	Cystic fibrosis with homozygous F508del mutation or ≥1 CFTR gene mutation that is responsive to tezacaftor/ivacaftor based on clinical and/or in vitro assay.	≥ 6 years	6 to <12 years, <30kg: 1 tablet (50mg/75mg) every morning and 1 ivacaftor tablet (75mg) orally every evening. 6 to <12 years, ≥30kg: 1 tablet (100mg/150mg) every morning and 1 ivacaftor 150mg tablet orally every evening. ≥12 years: 1 tablet (100mg/150mg) every morning and 1 ivacaftor 150mg tablet orally every evening.	N/A

SQ = subcutaneously

References

DRAFT PA Criteria

1. Arikayce (amikacin liposome inhalation suspension) [prescribing information]. Bridgewater, NJ: Insmed; March 2020.
2. Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: Greenwich Biosciences, Inc.; Nov 2018.
3. Onfi (clobazam) [prescribing information]. Deerfield, IL: Lundbeck; Jun 2018.
4. Sympazan (clobazam) [prescribing information]. Warren, NJ: Aquestive Therapeutics; Nov 2018.
5. Xgeva (denosumab) [package insert]. Thousand Oaks, CA: Amgen, Inc.; Feb 2020.
6. Nuedexta (dextromethorphan/quinidine) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc. June 2019.
7. Trikafta (elexacaftor/tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; October 2019.
8. Viberzi (eluxadoline) [package insert]. Madison, NJ: Allergan USA, Inc.; June 2018.
9. Kalydeco (ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; April 2019.
10. Orkambi (lumacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; July 2019.
- ~~11.~~ Increlex (mecasermin) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; Dec 2019.
12. Ofev (nintedanib) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; Mar 2020.
- ~~2.~~13. Osphena (ospemifene) [package insert]. Florham Park, NJ: Shionogi Inc.; Jan 2019.
14. Esbriet (pirfenidone) [package insert]. South San Francisco, CA: Genentech USA, Inc.; July 2019.
15. Banzel (rufinamide) [package insert]. Woodcliff Lake, NJ: Eisai, Inc.; Nov 2019.
16. Vesicare LS (solifenacin succinate) [prescribing information]. Northbrook, IL: Astellas Pharma US; May 2020.
17. Diacomit (stiripentol) [package insert]. Beauvais, France: Biocodex; Aug 2018.
18. Xermelo (telotristat ethyl) [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc.; Feb 2017.
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- ~~4.~~ Kalydeco (ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; April 2019.
- ~~5.~~ Orkambi (lumacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; July 2019.
- ~~6.~~19. Symdeko (tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; ~~June~~ Dec 2019.
- ~~—~~ Osphena (ospemifene) [package insert]. Florham Park, NJ: Shionogi Inc.; Jan 2019.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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